UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CHRISTINE VITELLO, on behalf of herself and others similarly situated,	)	
Plaintiff,	)	Case No. 4:18-cv-915
-vs-	)	**JURY TRIAL DEMANDED**
NATROL, LLC, a Delaware corporation,	)	
Defendant.	)	

AMENDED CLASS ACTION COMPLAINT

COMES NOW, Christine Vitello, individually and on behalf of others similarly situated, by and through counsel, and pursuant to the Court's Order [Dkt. #79] files this Amended Class Action Complaint adding and editing membership information for Defendant in Paragraphs 4 & 5 below. For Plaintiff's cause of action against Defendant, Plaintiff states as follows:

INTRODUCTION

1. This is a Missouri Merchandising Practices case, Chapter 407, et seq., and Unjust Enrichment claim against Natrol, LLC, which seeks to secure redress for unlawful merchandising practices and representations concerning its product Cognium, a dietary health supplement.

2. Defendant's product, Cognium allegedly improves memory and concentration for the consumer who ingests the product twice daily over a period of four (4) weeks, with Defendant advertising that nine (9) clinical studies support such claims when in fact two (2) of such clinical studies were retracted for fraud/fabrication and data manipulation.

3. Plaintiff seeks damages for herself and establishment of a Missouri Consumer Subclass and a Nationwide Class along with an order enjoining future unlawful activities and representations of Defendant concerning its product Cognium.

4. Defendant Natrol, LLC is a limited liability company organized under the law of the State of Delaware. Natrol's sole member is Aurobindo Pharma USA, Inc. Aurobindo Pharma USA, Inc. is a Delaware corporation with its principle place of business in New Jersey.

5. Defendant Natrol, LLC is registered with the State of California and has its headquarters located at 21411 Prairie Street, Chatsworth, California 91311.

6. Defendant offers its product Cognium to consumers throughout the United States, online and at various retail locations including Walgreens and Walmart.

VENUE & JURISDICTION

7. This Court has jurisdiction under 28 U.S.C. §1332, as Defendant is a resident of the State of California, and Plaintiff is a resident of the State of Missouri, and the amount in controversy exceeds the sum or value of $5,000,000 under the Class Action Fairness Act.

8. Venue and personal jurisdiction in the Eastern District of Missouri are proper pursuant to 28 U.S.C. §§ 1391 (a) and (b), because Defendants conducted business in this District and a substantial portion of the events that led to this cause of action occurred within this District.

9. Defendant's product Cognium is offered for sale throughout the St. Louis area, and the State of Missouri through its online sellers and retailers including Walgreens and Walmart.

10. Plaintiff Christine Vittelo is a natural person who is a citizen and resident of the State of

Missouri, who purchased Cognium at a Wal-Mart near her residence in June of 2017.

FACTS
THE NUTRACEUTICAL INDUSTRY-A MULTI BILLION DOLLAR UNREGULATED BUSINESS:

11. Defendant Natrol, LLC manufactures vitamins and supplements, otherwise known as "nutraceuticals" for a variety of uses, such as diet and weight management, sports nutrition, beauty, digestive health, immune support, eye health, sleep support, men's health, women's health- and brain health.

12. Defendant Natrol, LLC distributes its products nationally through more than 54,000 retailers across the United States, making its products available in health food stores, grocery stores and drug stores, and various online retailers, according to Defendant's company profile on Bioportfolio (www.bioportfolio.com/corporate/company/489/Natro-Inc.html)

13. The global market for Nutraceuticals was valued at approximately 383.06 Billion Dollars in 2016 and is expected to reach 561.38 Billion Dollars by 2022, according to a report published in December of 2017 ("Global Nutraceuticals Market-Growth, Trends and Forecasts (2017-2022)" see www.mordorintelligence.com/industry-reports).

14. The consumer demand for cognitive enhancing supplements is expected to increase, as the Nutrition Business Journal placed the value of such supplements or nutraceuticals at just under 1 Billion Dollars in the United States in 2010, which grew to 1.2 Billion in 2014. The expected growth of the market for cognitive enhancing supplements is expected to increase to almost 1.5 Billion Dollars by 2020. ("Cognitive Sup Sales Growing, Can Grow More" by Todd Runestead, Oct. 21, 2015

www.newhope.com/supplements/cognitive-sup-sales-growth).

15. In 2015, the New York Times reported on Congressional oversight and scrutiny of the nutraceutical industry, spearheaded by United States Senator Claire McCaskill of Missouri, who expressed concern over the representations made regarding various supplements, including those which claim to enhance memory, requesting information and documentation from 15 purveyors of nutraceuticals to be reviewed by the Special Committee on Aging ("Alzheimer's Supplements Targeted by U.S. Senator" by Anahad O'Connor, June 19, 2015, New York Times –well.blogs.nytimes.com).[1] (EXHIBIT 1, New York Times Article attached hereto, and incorporated by reference herein along with all exhibits identified below and herein)

16. In that same New York Times article, Senator McCaskill stated that "concerns have been raised that the F.D.A.s current regulatory authorities lack a systematic approach to preventing adulterated, mislabeled and fraudulent products from entering the market."

17. On or about March 7, 2017, Defendant released its product Cognium for sale to the public.

I. DEFENDANT'S REPRESENTATIONS-

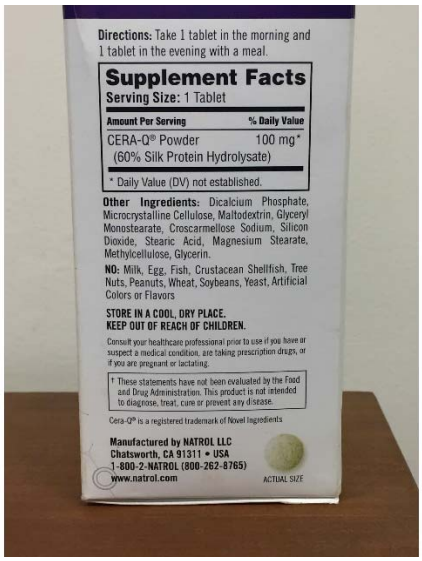
A. THE PACKAGING/ BOX OF NATROL COGNIUM

18. Defendant's product, Cognium is manufactured by Natrol, LLC, and is found inside a sealed box within which is a plastic bottle containing the product with additional information on a folded-up brochure pertaining to the alleged usefulness of the product.

[1] "People looking online for cures or treatment for Alzheimer's disease and dementia are at their most desperate- and it's clear from what we've found that many of these products prey on that desperation," said Senator McCaskill, the top-ranking Democrat on the Senate Special Committee on Aging. "Right now, it's like the wild west when it comes to the production, marketing, distribution and sale of these products. I want to figure out why that is and what we can do to better protect America's seniors."

19. The front of the box or packaging for Cognium shows "Brain Health" and immediately below it, the words "Natrol Cognium For A Sharper Mind", and informs the consumer that it is "Clinically Proven to Improve Memory and Concentration", and that it is "Stimulant Free" and "Results in 4 Weeks."

20. Defendant's Natrol Cognium packaging on one side of the box states that it contains 60 tablets, that are to be taken by the consumer twice each day, once in the morning and once in the evening, with the primary ingredient constituting 100 milligrams of CERA-Q Powder.



21. On the other side of the Natrol Cognium packaging, the consumer finds the words "Proven Results" and below that is a graph that purports to show the consumer how effective the product is in "Improving Memory and Performance", by showing a "Memory Recall Score" on the left hand side of the graph numbered from 0-20-40-60, while at the base of the graph, with memory recall without taking Cognium at number 20 (the "Without Cognium" column) whereas when Cognium is taken the column hits 60 and the additional claim of "90% Improvement". Immediately below that graph are the words "After 21 days Statistically significant results".

22. Below the graph is a description of the results: "Memory Recall Efficiency score increased 90% when 100 mg of Cera-Q, the protein in Cognium, was taken twice per day for three weeks. Detailed Results can be found at: www.Cera-Q.com." Reading further below that representation, is the claim "RESULTS IN 4 WEEKS" and further stating that "Nine clinical studies in adults, seniors and children showed statistically significant improvements in memory and cognition in 4 weeks or less when taken as directed."

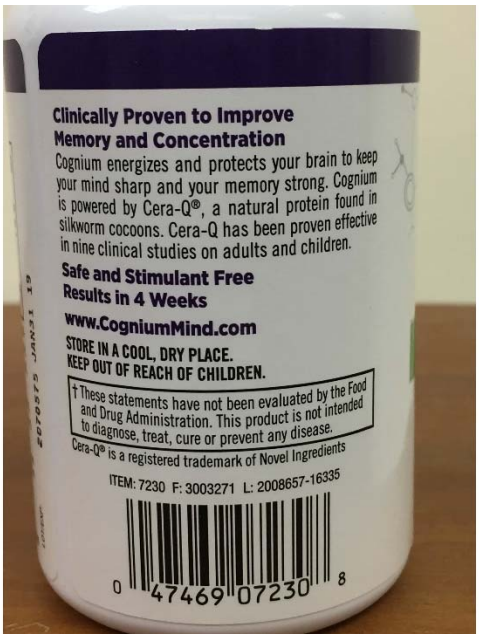
23. Defendant represents and advertises on the back of the box or package that Natrol Cognium is alleged to contain and is "powered" by CERA-Q Powder, which is "a natural protein from silkwork cocoons. Its unique structure allows it to work with receptors in your brain to support brain health and cognition. It has been clinically proven effective in nine human studies."

24. On the back of the box or package, Defendant represents that its product "Energizes" and "Increases blood flow and nutrition to the brain's centers for memory and cognition" and that it "Protects" and "Acts like an antioxidant for your brain, shielding it from free radical damage" while informing the consumer that "Cognium nourishes, energizes and protects your brain to keep your mind sharp and your memory strong."

B. THE PRODUCT CONTAINER/BOTTLE FOR NATROL COGNIUM

25. The product container holding the tablets is labeled in three areas, and prominently on the front of the container are the words "BRAIN HEALTH", "NATROL COGNIUM" "FOR A SHARPER MIND" and "Clinically Proven to Improve Memory and Concentration"

26. On one side of the bottle/container are "Supplement Facts" that restate the contents of the product described on the packaging or box the container is sealed within, while the other side of the bottle states in bold lettering "Clinically Proven to Improve Memory and Concentration" and further states "Cognium energizes and protects your brain to keep your mind sharp and your memory strong. Cognium is powered by Cera-Q, a natural protein found in silkworm cocoons. Cera-Q has been proven effective in nine clinical studies on adults and children." The consumer is also informed the product is "Safe and Stimulant Free" and provides the website address for www.CogniumMind.com.



C. THE BROCHURE FOR NATROL COGNIUM

27. Upon opening the packaging, the consumer finds on top of the container of tablets a brochure that is folded up, and when removed from the box are the words “BRAIN HEALTH”, “NATROL COGNIUM” “FOR A SHARPER MIND” (EXHIBIT 2-Front of Brochure).

28. When the brochure is unfolded, it has statements about the product’s memory enhancing benefits, informing the consumer “Welcome to a Sharper Mind”, congratulating the consumer on their purchase and stating that the product is “Backed by a natural ingredient that has nine clinical studies showing statistically significant improvements in memory and cognition, cognium is the wise choice in brain health supplements.” Consumers are further advised to “Keep reading for . . . The science behind Cognium and how it works.” (EXHIBIT 2).

29. Unfolded, the brochure is approximately 8 ½ by 11 inches, and on the front side prominently displays a coupon, along with “Tips and Resources” for consumers to follow

for "caring" for their brain (EXHIBIT 2).

30. On the side of the brochure without the coupon, the consumer is provided with "How Cognium Sharpens your Mind". The reader is informed in bold, 30 point font that Cognium "ENERGIZES", "PROTECTS" and the consumer is also provided with 'BRAIN FACTS." (EXHIBIT 3-Back of Brochure).

31. One of the statements made by Defendant concerning how the product allegedly will "sharpen" a consumer's mind, is found under the section labeled "THE SCIENCE". Consumers reading are again reminded that:

> "The natural silk protein that powers Natrol Cognium has been extensively studied and proven effective. Nine human clinical studies showed statistically significant improvements in memory, concentration and other cognitive functions in both males and females ranging from children to seniors."

Defendant continues its representations of the "Science" in the next paragraph, claiming:

> "The majority of studies were randomized, double-blind, placebo-controlled studies and meet the highest level of evidence for claims support as stated by both the FDA and FTC. The studies were published in 11 peer-reviewed reports. A list of studies can be found on www.cera-q.com."

(EXHIBIT 3).

32. Defendant's brochure also provides the consumer with "FAQs" concerning the product, informing the consumer that Cognium is "powered" by Cera-Q, which is purported to be a silk protein found in silkworm cocoons making it "particularly effective" in support of the brain (EXHIBIT 3).

33. Next, Defendant's brochure addresses another question for the consumer-"Is Cognium Safe?" Defendant informs the consumer that: "Cognium is safe, natural and stimulant free. Silk proteins, like the one in Cognium, have been safely used in Eastern medicine for hundreds of years. In the early 2000s, a team of PhD researchers in South Korea

actively studied these proteins, which led to the discovery of Cera-Q and its connection to brain health." (EXHIBIT 3).

34. After informing the reader that the product is "safe", the next question asked and answered by the Defendant concerning its product is -"Is there scientific proof that Cognium Works?" Defendant answers: "Nine human clinical studies on Cera-Q showed statistically significant improvements in memory and cognition in adults and children. The results can be found on www.cera-q.com. (EXHIBIT 3).

35. Defendant's brochure also addresses questions concerning when a consumer should "see results", claiming that "Results were seen within 3-4 weeks when taken as directed. Every individual is different so results may vary from person to person." (EXHIBIT 3).

36. Defendant's brochure advises consumers that if they want more information about Cognium, they can visit www.CogniumMind.com.

D. Defendant's website www.CogniumMind .com

37. Consumers are encouraged to review Defendant's website www.CogniumMind.com for additional information about Natrol Cognium, and such website is identified on the packaging/box, container/bottle, and the brochure. (EXHIBIT 3; Complaint Pages 7 & 9).

38. When the product was initially released and for a period of months thereafter, when clicking on the website, the consumer was presented with a webpage that announced "STAY SHARP", and informed that "Caring for your mind is now a no brainer. Natrol Cognium energizes and protects your brain to keep your mind sharp and your memory strong. The only brain health supplement with an ingredient that's backed by 9 human clinical trials, Cognium is the smart choice in brain health." (EXHIBIT 4-Original Webpage www.CogniumMind.com "Stay Sharp").

39. On that very same webpage, the consumer is also informed that the product has "Clinically Proven Results", and that "In nine human clinical studies, Cognium's unique silk protein has shown statistically significant cognitive improvements in adults, seniors and children in as little as weeks when taken as directed. Learn More." (EXHIBIT 4).

40. Defendant's tout the product is "Safe and Effective", again pointing out to the consumer that ". . . Cognium has been proven safe and effective in nine human clinical trials." (EXHIBIT 4).

41. However, as of the date of filing of this Class Action Complaint, the www.CogniumMind.com website has been altered substantially by Defendant sometime after June 15, 2017. Now, the words "nine human clinical trials" have been removed. Instead the website uses the phrase "human clinical trials." In addition, Defendant no longer makes any reference to human clinical trials for supporting its claim that the product is "Safe & Effective". Defendant also provides a link to the "Natrol Cognium Clinical Studies" at the bottom of the web page, under "Additional Tips & Tools"(EXHIBIT 5-Revised Webpage www.CogniumMind.com "Stay Sharp").

42. Another example of the revisions to Defendant's website includes the omission of what was once touted as its claim of a "Brain Health Protein", where the consumer was informed that "Caring for your mind is now a now brainer. Natrol Cognium energizes and protects your brain to keep your mind sharp and your memory strong. The only brain health supplement with an ingredient that's backed by 9 human clinical trials, Cognium is the smart choice in brain health." This same page touted the same 9 human clinical trials as its representations for the product's "Clinically Proven Results" and reinforcing to consumers that the product is "Safe and Effective" (EXHIBIT 6-Original Webpage,

www.CogniumMind.com "Brain Health Protein").

43. Now, the current website lacks that particular page, and instead each and every page shows the words "human trials", instead of "9 human clinical trials". On the "Stay Sharp" web page, consumers are encouraged to click on the "Learn More" and are directed to a webpage which depicts the product in its package, and claims that its product is "A breakthrough in brain health, Natrol Cognium is powered by a unique ingredient backed by human clinical studies that show statistically significant improvements in memory and cognition in as little as four weeks." Consumers can then click on a link directing them to "Find a Retailer" and "View Coupon" (EXHIBIT 7-Revised webpage www.CogniumMind.com "Product Descrpition/FAQS").

44. On that same revised webpage consumers are presented with a "Product Description" which represents that the product is "backed by human clinical studies that show statistically significant improvements in memory and cognition in as little as four weeks. Results have been published in respected, peer reviewed journals. Cognium is safe, natural and stimulant free." Defendant further claims that its product has "#1 most clinically studied ingredient-human clinical studies" (EXHIBIT 7).

45. Consumers are presented with "FAQs" which are geared toward answering questions consumers may have about the product and relying again on the "human clinical studies", again defining what Cognium is, when it should be ingested, when results will be seen. In answer to the question "Is Cognium Safe", the consumer is informed:

> A: Cognium is safe, natural and stimulant-free. Silk proteins, like the one in Cognium, have been safely used in Eastern medicine for hundreds of years. In the early 2000s, a team of PhD researchers in South Korea actively studied these proteins, which led to the discovery of Cera-Q and its connection to brain health."

(EXHIBIT 7).

46. Defendant, anticipating that consumers will question whether or not the product actually works, provides an answer to the question on its revised webpage: "Is there scientific proof that Cognium works? A: Human clinical studies on Cera-Q showed statistically significant improvements in memory and cognition of in adults and children." (EXHIBIT 7).

47. On each revised web page, the consumer can click on "Product by Ingredient" located at the top of each page, and when clicking on "Cognium" are presented with a web page titled "COGNIUM", representing that it is "an ingredient that's clinically proven to improve memory and concentration", further claiming that the product is a "breakthrough in brain health" and "is powered by a unique ingredient backed by human clinical studies that show statistically significant improvements in memory and cognition in as little as four weeks." At the bottom of the page is link to "Natrol Cognium Clinical Studies" under "Additional Tips & Tools" (EXHIBIT 8-Product by Ingredient www.CogniumMind.com).

48. On each web page, the consumer can click on "Product by Health Benefit" located at the top of each page, and when clicking on "Brain Health", the consumer is directed to the web page with the words "STAY SHARP" (EXHIBIT 5).

49. On each web page described above, consumers have the opportunity to click on a link for "Natrol Cognium Clinical Studies", located at the bottom of each web page under "Additional Tips & Tools". Clicking on "Health Tips & Tools" at the top of each page brings you to another webpage with articles for the consumer to review, including one titled "Brain Health- Natrol Cognium Clinical Studies". Defendant has made substantive changes to its website since it began marketing Cognium, removing numerous

representations concerning the clinical studies before the filing of this Complaint.

50. Prior to March 2018, on the page titled "NATROL COGNIUM CLINICAL STUDIES", the consumer views a photograph of three women smiling, playing a game of cards at a table, immediately below which is the bar graph previously depicted on the side of the packaging of the product described above, and again directing the consumer that "Detailed results can be found at: www.Cera-Q.com". Next to the bar graph, the consumer is informed:

> Natrol Cognium features a silk protein hydrolysate that has been extensively studied and proven effective. The majority of studies were randomized, double-blind, placebo-controlled studies that meet the highest level of evidence for claims support as stated by both the FDA and FTC. The studies were published in 9 respected peer-reviewed journals that can be found below. In these clinical studies, the silk protein in Cognium is referred to as either Brain Factor-7 or BF-7.

Immediately below this text, the consumer views "Cognium Clinical Studies", numbering one (1) through nine (9), with clinical study numbered 7 being a "Combined Report" of three studies. Next to each number are the names of the researchers allegedly involved in the study, along with the name of the study, and the name and/or abbreviation of the publication or journal which published the study, along with the year and pages where the study is located for review (EXHIBIT 9- Original Citation-"Natrol Cognium Clinical Studies").

51. None of the nine (9) "Cognium Clinical Studies" provided a link to the actual text of the published study (EXHIBIT 9).

52. Part of the Combined Report described above in Cognium Clinical Study #7, titled "*Neuroprotection and Enhancement of Learning and Memory by BF-7*", published in 2005 was retracted by the publisher of such study, the Journal of Health Science on

September 15, 2009, at the request of the researchers involved in the study. The Authors' Comments are as follows:

> We deeply regret that part of the experimental data we previously published in the Korean Journal of Physiology and Pharmacology, 8, 173-179, August (2004) was included in the above mentioned article by mistake.
>
> Therefore, we would like to withdraw this article written by Dao Kyong Kim, Yong Koo Kang, Moo Yeol Lee, Kwang-Gill Lee, Joo-Hong Yeo, Won Bok Less, Yong Sik Kim, and Sung Su Kim from the Journal of Health Science.

(EXHIBIT 10-Retraction –Data Manipulation Natrol Cognium Clinical Study # 7). The data "previously published" refers to Clinical Study # 3 (EXHIBIT 9).

53. Natrol Cognium Clinical Study #8, titled "*Memory Enhancing Effects of Silk Fibroin Derived Peptides in Scopolamine Treated Mice*", published by the Journal of Microbiology and Biotechnology in 2013 was retracted for:

> Misconduct of the authors (data fabrication and falsification). JMB as the publisher regrets for any inconvenience caused by the retraction.

(EXHIBIT 9; EXHIBIT 11 Retraction Fabrication/Falsification; EXHIBIT 12- Retracted Article).

54. The Journal of Microbiology and Biotechnology defines "Fabrication" as "The creation of false information about non-existent data or findings." Whereas, "Falsification" is defined as "The artificial manipulation of research materials, equipment, and processes; and/or the modification or deletion of data resulting in distorted research or research results." (EXHIBIT 13- Research Misconduct Policy, Journal of Microbiology and Biotechnology).

55. None of Defendant's advertising, packaging, containers, brochures or website inform

consumers that two of the nine Natrol Cognium Clinical Studies were retracted, and the reasons for such retraction.

56. None of Defendant's advertising informs the consumer that two (2) of the clinical studies were retracted, and that one such clinical study retracted was part of a "Combined Report" involving two (2) other studies.

57. As of early March 2018 Defendant's webpage only showed eight (8) Cognium Clinical Studies- not nine (9), with the two primary clinical studies that were retracted identified above removed from the webpage. The identity of the researchers is also omitted from the citation. (Compare EXHIBIT 9 with EXHIBIT 14 -Revised Citation Natrol Cognium Clinical Studies).

58. The remaining Cognium Clinical Studies that were not subject to retraction involve the same researchers that participated in the retracted studies, and many of the remaining studies directly cite, or rely upon the retracted studies for the alleged results showing Cognium is statistically significant and/or "clinically proven".

59. One of the studies that was not withdrawn from Defendant's website is Clinical Study #1, titled "*Brain Factor-7 Extracted from Bombyx mori Enhances Cognition and Attention in Normal Children*" (EXHIBIT 9; EXHIBIT 14).

60. Robert Speth, another researcher who reviewed Cognium Clinical Study #1 concerning Defendant's advertisement of "proven results, improving memory & performance" concluded that

> "Upon reviewing this paper, I find the results to be suspect and not supportive of the claims that the active ingredient in Natrol Cognium significantly enhances cognitive performance"

Speth opined further that "it is difficult to believe that a 1.7% improvement would be

statistically significant or clinically meaningful", concluding that "this report does not support the advertising claims that Natrol Cognium is clinically shown to improve cognitive performance." (EXHIBITS 15-Review of Robert Speth for NCBI dated July 10, 2017; 9; 14).

61. Cognium Clinical Study #1- "*Brain Factor-7 Extracted from Bombyx mori Enhances Cognition and Attention in Normal Children*" is linked to the webpage and involves Sung-Su Kim, one of the researchers involved in the study retracted for data manipulation. In addition, this particular Clinical Study cites directly to the retracted study at Reference # 23 on page 647, "*Neuroprotection and enhancement of learning and memory by BF-7*", and is cited liberally throughout Clinical Study #1:

In the Introduction, at pages 643 and 644-

> Recently, it has been reported that brain factor-7 (BF-7), a natural extract from Bombyx mori, exerts significant improvement on cognitive and protective functions of the nervous system. 19-25
> ---
>
> It has been suggested that BF-7 improves memory function of normal and demented persons and protects SK-N-SH human neuroblastoma cells from reactive oxidative stress. 22, 23

In the Discussion, at page 646:

> Many previous reports indicate that BF-7 enhances learning and memory and attention in juveniles and normal adults. 23, 24

(EXHIBIT 16, Clinical Study #1 see highlighted text; EXHIBITS 10, 9, 14).

62. Cognium Clinical Study #1 was accepted for publication on February 12, 2009, and Sung-Su Kim's study "*Neuroprotection and enhancement of learning and memory by BF-7*" was retracted on September 15, 2009. However, Sung-Su Kim, the researcher involved in both the retracted study, and Revised Cognium Clinical Study #1 failed to

notify the Journal of Medicinal Food that the research he cited was retracted for data manipulation. (EXHIBIT 16, p. 643 see highlighted text; EXHIBITS 10, 9, 14).

63. Cognium Clinical Study #4-"*Milk Containing BF-7 Enhances the learning and memory, attention, and mathematical ability of normal persons*", directly references the retracted study as noted under the References section at numbers 8, p. 281 author DK Kim, 2005 (EXHIBIT 17-Clinical Study #4, see highlighted text), which was retracted for manipulation of data-including data from another study (EXHIBIT 10). The Reference is used in the following manner in the Introduction of the study:

> Many lines of evidence, including those from controlled clinical studies, suggest that BF-7, a natural extract from Bombyx mori, can significantly improve learning and memory in normal persons and can enhance the function of the nervous system (Chae et al., 2004; Kim et al, 2005; Lee et al., 2004a) -p. 278.
>
> It has also been suggested that BF-7 can improve the memory function of demented persons and can protect human neuroblastoma cells from reactive oxidative stress (Kim et al., 2005; Lee et all., 2004a) - p. 278.

Defendant has failed to provide information on its website that such study was supported with another retracted study.

64. Cognium Clinical Study #7 references two (2) clinical studies- as a "Combined Report"- "*The Improvement of learning and memory ability of normal persons by BF-7*" and "*The effect of BF-7 on the ischemia-induced learning and memory deficits*". These were originally part of a "Combined Report" of three studies, or Clinical Study #7 that was retracted (EXHIBITS 14, 9 & 10), involving the same researchers involved in the retracted studies, and Defendant makes no reference on its current website that such two studies were directly linked with another study that was retracted, or that the two studies in question were part of a "Combined Report" and are now identified separately.

65. Sometime again in March of 2018, Defendant again altered its webpage concerning the Cognium Clinical Studies, reducing the number from eight (8) to five (5), omitting the retracted studies discussed above, and separating the "Combined Report" into separate study listings. (EXHIBIT 18-Revised Cognium Clinical Studies; compare to EXHIBIT 14 and EXHIBIT 9).

66. At some time after reducing the Cognium Clinical Studies to five (5), the Defendant then changed its website to identify only four (4) Cognium Clinical Studies, removing the names of the authors of the studies from the website (EXHIBIT 19-Revised Cognium Clinical Studies).

E. Defendant's Website link to - www.cera-q.com.

67. On one side of the packaging/box which houses the pill container, directly below the bar graph showing the consumer that Cognium increases your memory score by 90%, consumers are informed that "Detailed results can be found at: www.Cera-Q.com."

68. Entering the webpage, the consumer finds various links for "How It Works", "Products & Applications", "Clinical Studies", and "FAQS", while informing the reader "Stay Sharp" with additional links provided. At the bottom of the page in large font, the following language is found:

> CERA-Q IS BACKED BY 9 HUMAN CLINICAL TRIALS DEMONSTRATING SIGNIFICANT COGNITIVE IMPROVEMENTS ACROSS A WIDE RANGE OF AGES IN JUST 3 TO 4 WEEKS. CLICK TO LEARN MORE ABOUT THESE CLINICALLY DEMONSTRATED RESULTS.

(EXHIBIT 20, Cera-Q Web page "Stay Sharp-Function, Focus Freedom).

69. Clicking on the "Learn More" link found directly to the left of the representation noted above in EXHIBIT 20, the consumer is faced with a

web page titled "Clinical Studies", which again touts the existence of clinical data:

> Comprising bioactive peptides with a unique amino acid profile, Cera-Q is backed by 9 published human clinical trials and in vitro data, all of which demonstrate Cera-Q's support of memory, learning, and general cognitive function across a wide range of ages, from children to the elderly. These studies show significant results in 3-4 week trials, demonstrating that Cera-Q is a powerful natural solution to help improve brain health at every age.

(EXHIBIT 21-Cera-Q Webpage link "Clinical Studies"). On that same webpage "Clinical Studies", are found a variety of bar graphs purporting to depict the results of these nine clinical studies, along with photographs that show adults and children concentrating on various tasks.

70. At the bottom of the Cera-Q webpage is the link "Key Published Research" which purportedly supports the representations made on the webpage, and when the link is clicked the consumer views eight (8) "published studies", despite the representation on that same page that there are "nine published human clinical trials" (EXHIBIT 21).

71. Reviewing the "Key Published Research" shows that the clinical study that was retracted for fraud-"*Memory Enhancing Effects of Silk Fibroin Derived Peptides in Scopolamine Treated Mice*" -is referenced as supporting Defendant's representations as study #2 (EXHIBIT 11, 21).

72. Further review of the "Key Published Research" shows that the clinical study that formed the basis for one of the retracted studies is referenced as study #1, "*The Role of BF-7 on Neuroprotection and Enhancement of Cognitive Function*", which was the underlying basis for the retraction of the study titled "*Neuroprotection and Enhancement of Learning and Memory by BF-7*" (EXHIBIT 10, 21).

73. Clinical Study #1 is referenced or repeated again as Study # 7 in the "Key Published Research" (EXHIBIT 21).

74. Here, on the Key Published Research, the "Combined Report" found in Cognium Clinical Studies is not referenced, and instead the other two studies that were combined with the retracted report are referenced independently, as Study # 4 "*The Effect of BF-7 on the Ischemia-induced Learning and Memory Deficits*" and Study #8 "*The Improvement of Learning and Memory Ability of Normal Persons by BF-7*" (EXHIBIT 21; Compare to EXHIBIT 9, Cognium Clinical Studies).

75. Defendant represents that "Cera –Q is backed by 9 published human clinical trials", when in fact the Key Published Research reveals: a) one study retracted for fraud, b) two other studies that are part of a "Combined Report" that was also retracted, and c) one study that was referenced twice which was the basis for retracting the "Combined Report", leaving at most four (4) studies that were not subject to retraction. (EXHIBITS 21, 11, 9, 10).

76. When the consumer clicks on the link for "FAQS", the page appears offering the question "Is Cera-Q Beneficial for All Ages?" and defendant again makes representations concerning the number of clinical studies:

> The published research on Cera-Q demonstrates safety and efficacy across a full range of ages in normal, healthy people representative of the general population. Children, high school and college students, adults from 13-70 years old, and seniors over 70 years old were studied in nine separate studies. They were given standardized and scientifically accepted tests to measure benefits and changes for different kinds of shorty-term memory, learning skills, and complex tasks, measures typically used in IQ tests. Significant improvements were demonstrated at both intake levels (200 and 400 mg daily in two divided doses) in just three to four weeks- a short time for seeing results.

(EXHIBIT 22- Cera-Q "FAQS")(Emphasis added).

F. Defendant's Press Releases concerning Cognium

77. On or about March 7, 2017, Defendant released its product Cognium for sale to the public, and in a press release alleged that "Natrol Cognium is the only brain health supplement with a proven nutrient backed by 9 clinical trials that show statistically significant improvements in memory and cognition in four weeks or less" (EXHIBIT 23-p. 2, "Natrol, LLC Announces Breakthrough Cognitive Health supplement Cognium at Expo West 2017"(March 7, 2017).

78. In that same press release, Defendant's representative, David Hilton, director for Research and Development for Natrol, LLC stated that "We're especially proud of the research and clinical studies that support that the ingredients in Cognium can improve cognitive health" (EXHIBIT 23, p. 3).

79. On June 12, 2017 Defendant released another press release, titled "Natrol LLC Introduces Natrol Cognium, A Breakthrough Brain Health Supplement" touting that the product was "Backed by nine human clinical trials, Natrol Cognium Improves Memory and Cognition" (EXHIBIT 24, p. 1, Business Wire).

80. In the press release from June 12, 2017, Defendant claims "This breakthrough product is specifically formulated to keep your mind sharp and your memory strong. Backed by nine human clinical studies, the active ingredient in Natrol Cognium has shown statistically significant improvements in memory and cognition in as little as four weeks." (EXHIBIT 24, p. 2).

81. Defendant's CEO, Tom Zimmerman stated in the press release dated June 12, 2017 that "From forgetting names of friends or colleagues to struggling for a word, we all have those moments where we could use something to keep our memory strong and our minds

sharp. People can use Natrol Cognium to proactively manage and own their everyday health and help them face real issues they're dealing with in their busy lifestyles as they age." (EXHIBIT 24, p. 3).

82. In an internet posting from June 29, 2017, Defendant's marketing team discussed its marketing approach to Natrol Cognium claiming that "The active ingredient in the product itself is tested in nine human clinical trials, and this is the key component of our messaging to ensure that our target feels that the product is credible and proven", according to Tori Young, Phelps VP of Strategy (EXHIBIT 25- "Pharma Marketing: Natrol Promotes Staying Sharp, Not Young" by Sheila Shayon).

83. Ms. Shayon's posting of June 29, 2017 also reiterates the claims of Defendant that "Cognium is backed by 9 human clinical studies that show statistically significant improvements in memory and cognition in as little as four weeks. Results have been published in respected, peer-reviewed journals." (EXHIBIT 25).

84. Defendant's Senior Manager for Brand Innovation, Michelle Baron claims that "Cognium has been show to be safe and effective in a wide variety of age groups. While our advertising is targeted towards the senior population, adults of all ages will benefit. It is something that should be taken daily and it has a cumulative effect over time." (EXHIBIT 25).

85. Defendant's representative, Ms. Baron goes on to state that "With Cognium, as with any product we bring to market, we need to make sure that our benefits and claims are truthful and not misleading. That's not only to comply with FTC guidelines, but also consistent with ethical and responsible business management." (EXHIBIT 25)

86. Ms. Baron went further, and stated that:

For Cognium, we specifically selected an ingredient that had nine human clinical studies that showed statistically significant improvements in memory and other cognitive functions. The clinicals were high quality studies, with the bulk being randomized, placebo-controlled, double blind studies- high quality studies- that used scientifically accepted measures and tests for cognitive performance and that were published in respected peer-reviewed journals. Additionally, we formulated Cognium to ensure we used a clinical dose and our usage instructions mirror those used in the clinical studies. Our claims and are product are consistent with what was used and what was shown in the studies."

(EXHIBIT 25).

CAUSE OF ACTION
COUNT 1.

I. Violation of the MISSOURI MERCHANDISING PRACTICES ACT ("MMPA")

87. Plaintiff Vitello incorporates the aforementioned allegations set forth above in paragraphs 1 through 86 as if directly reproduced herein.

88. Plaintiff Vitello purchased Cognium in June of 2017 from a Wal-Mart near her residence at the price of $19.97.

89. Plaintiff Vitello's purchase of Cognium constitutes "merchandise" as defined under §407.010 of the Missouri Merchandising Practices Act.

90. Plaintiff Vitello took the Cognium according to the directions on the packaging/box, and bottle, and read the information on the box/packaging, brochure, bottle, and reviewed the websites identified by the Defendant on its packaging, bottle and brochure.

91. Plaintiff Vitello did not experience any improvement in her memory, concentration or cognition at any time while taking the Cognium for thirty (30) days.

92. Plaintiff Vitello would not have purchased the Cognium if Defendant had not made the representations concerning its product as set forth above and reincorporated herein and has been damaged in an amount to be determined at trial, including an award of punitive damages due to Defendant's conduct as described above and below herein.

93. Plaintiff Vitello has suffered an ascertainable loss, as the value of the Cognium as purchased was less than the value of the Cognium as it was represented above.

94. The Defendant's conduct as described above and incorporated herein was outrageous due to Defendant's evil motive or reckless indifference to the rights of the consumers who purchased Cognium, entitling Plaintiff Vitello and putative class members to an award of punitive damages under Mo. Rev. Stat §407.025 and §510.265.

95. Plaintiff Vitello and the putative class members are entitled to an award of punitive damages in the amount that is five (5) times their actual damages or $500,000 per violation, whichever is greater under Mo. Rev. Stat. §510.265.

96. Plaintiff Vitello would not have purchased the Cognium and sustained the loss had the Defendant disclosed in its box/packaging, bottle, and brochure that two (2) of the nine (9) clinical studies had been retracted for data manipulation and fraud/fabrication.

97. Plaintiff Vitello would not have purchased the Cognium and sustained the loss had the Defendant disclosed that the remaining unretracted studies directly cited to or referenced the retracted studies as support for the clinical results allegedly achieved or obtained.

98. Plaintiff Vitello would not have purchased the Cognium and sustained the loss had the Defendant disclosed in its box/packaging, bottle, and brochure that its alleged results were supported by fewer than nine (9) clinical studies.

99. Plaintiff Vitello would not have purchased the Cognium and sustained the loss had the Defendant disclosed that the authors, or researchers involved in the retracted studies were also involved in the remaining studies.

100. Plaintiff Vitello would not have purchased the Cognium and sustained the loss had the Defendant disclosed in its box/packaging, bottle, and brochure that its claim of "Proven

Results", "Clinically Proven" and "90 Percent Improvement" were based on two (2) retracted studies.

II. Violations of the MMPA-Unfair Practices- Product packaging/box.

101. Defendant violated § 407.020 of the MMPA by representing and/or advertising that Cognium "has been clinically proven effective in nine human studies", as stated on the back of its product packaging/box when Defendant knew, or upon reasonable inquiry would have known, that two (2) of the Nine studies in question were retracted, making such representation an unlawful or unfair practice.

102. Defendant violated § 407.020 of the MMPA when it either concealed, omitted, or suppressed from its labeling and advertising materials the fact that one of the "nine clinical studies" was retracted for fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 9, 11, 12).

103. Defendant violated § 407.020 of the MMPA when it either concealed, omitted, or suppressed the fact that one of the "nine clinical studies" was retracted for including data that was previously published in another study "by mistake", when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 9, 10).

104. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the front of Cognium packaging/box that it is "Clinically Proven to Improve Memory and Concentration" when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or

unfair practice (EXHIBITS 10, 11, 12)

105. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the side of the Cognium packaging/box that the product has "Proven Results" when two of the clinical studies were retracted for data manipulation and fraud/fabrication, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 10, 11, 12).

106. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the side of the Cognium packaging/box that ingesting Cognium for 21 days shows "90% Improvement" in memory and performance when at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 10, 11, 12).

107. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the side of the Cognium packaging/box that ingesting Cognium "After 21 Days statistically significant results" when at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 10, 11, 12).

108. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the side of the Cognium packaging/box that "Memory Recall Efficiency score increased 90% when 100 mg of Cera-Q, the protein in Cognium, was taken twice per day for three weeks. Detailed Results can be found at: www.Cera-Q.com." Reading further below that representation, is the claim "RESULTS IN 4 WEEKS" and further stating that "Nine

clinical studies in adults, seniors and children showed statistically significant improvements in memory and cognition in 4 weeks or less when taken as directed." - when at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 10, 11, 12).

109. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the back of the Natrol Cognium packaging/box that Cognium is "powered" by CERA-Q Powder, which is "a natural protein from silkwork cocoons. Its unique structure allows it to work with receptors in your brain to support brain health and cognition. It has been clinically proven effective in nine human studies", when at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 10, 11, 12).

II. Violations of the MMPA-Unfair Practices- Product Container/Bottle.

110. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the front of the product container/bottle "BRAIN HEALTH" , "NATROL COGNIUM" "FOR A SHARPER MIND" and "Clinically Proven to Improve Memory and Concentration", when at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 10, 11, 12).

111. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the

side of the product container/bottle "Clinically Proven to Improve Memory and Concentration" and further states "Cognium energizes and protects your brain to keep your mind sharp and your memory strong. Cognium is powered by Cera-Q, a natural protein found in silkworm cocoons. Cera-Q has been proven effective in nine clinical studies on adults and children" when at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 10, 11, 12).

III. Violations of the MMPA- Unfair Practices-Brochure for Natrol Cognium.

112. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the Brochure included inside the product packaging/box that Cognium is "Backed by a natural ingredient that has nine clinical studies showing statistically significant improvements in memory and cognition, cognium is the wise choice in brain health supplements." when at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 2, 10, 11, 12).

113. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the Brochure included inside the product packaging/box that Cognium is "The natural silk protein that powers Natrol Cognium has been extensively studied and proven effective. Nine human clinical studies showed statistically significant improvements in memory, concentration and other cognitive functions in both males and females ranging from children to seniors." when at least two (2) clinical studies were retracted for data

manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 3, 10, 11, 12).

114. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the Brochure included inside the product packaging/box that Cognium "The majority of studies were randomized, double-blind, placebo-controlled studies and meet the highest level of evidence for claims support as stated by both the FDA and FTC. The studies were published in 11 peer-reviewed reports. A list of studies can be found on www.cera-q.com." when the studies on the webpage of www.cera-q.com are not 11, but only 8 where one of the studies is repeated twice making the total only 7, and where one of the listed clinical studies was retracted for fabrication/falsification and another study was the basis for data manipulation, while the remaining two studies associated with the retracted study were part of a "combined report" that was retracted, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 3, 21, 11, 12, 10).

115. Defendant violated § 407.020 of the MMPA by representing and/or advertising on the Brochure included inside the product packaging/box of Cognium asking and answering the question: -"Is there scientific proof that Cognium Works?" Defendant answers: "Nine human clinical studies on Cera-Q showed statistically significant improvements in memory and cognition in adults and children. The results can be found on www.cera-q.com." -when the studies on the webpage of www.cera-q.com are not 9, but only 8; where one of the studies is repeated twice making the total only 7, and where one of the listed clinical studies was retracted for fabrication/falsification and another study was the

basis for data manipulation, while the remaining two studies associated with the retracted study were part of a "combined report" that was retracted when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 3, 21, 11, 12, 10).

IV. Violations of the MMPA- Unfair Practices- Defendant's website www.CogniumMind.com.

116. Defendant violated § 407.020 of the MMPA when it either concealed, omitted, or suppressed the fact that it had changed its website www.CogniumMind.com sometime after the release of the product from referencing "nine clinical studies" instead using the phrase "clinical studies" when discussing its product when Defendant knew, or upon reasonable inquiry would have known of such changes to its website, making such representation an unlawful or unfair practice (EXHIBITS 4, 5, 6, 7).

117. Defendant violated § 407.020 of the MMPA when it either concealed, omitted, or suppressed the fact that it had changed its website www.CogniumMind.com sometime after the release of the product from identifying nine (9) Cognium Clinical Studies to eight (8) studies, omitting the two retracted studies when Defendant knew, or upon reasonable inquiry would have known of such changes to its website, making such representation an unlawful or unfair practice (EXHIBITS 9 & 14)

118. Defendant violated § 407.020 of the MMPA when it either concealed, omitted, or suppressed the fact that it had changed its website www.CogniumMind.com sometime after the release of the product from referencing nine (9) Cognium Clinical Studies to five (5) studies, when Defendant knew, or upon reasonable inquiry would have known of such changes to its website, making such representation an unlawful or unfair practice (EXHIBITS 9 & 18).

119. Defendant violated § 407.020 of the MMPA when it either concealed, omitted, or suppressed the fact that it had changed its website www.CogniumMind.com sometime after the release of the product from referencing nine (9) Cognium Clinical Studies to four (4) studies, when Defendant knew, or upon reasonable inquiry would have known of such changes to its website, making such representation an unlawful or unfair practice (EXHIBITS 9 & 19).

120. Defendant violated § 407.020 of the MMPA when it either concealed, omitted or suppressed the fact that the researchers involved in the retracted studies were also involved in the remaining studies that were not retracted, making the studies questionable as to the validity and reliability of the results obtained, when Defendant knew, or upon reasonable inquiry would have known of the involvement of such researchers, making such representation an unlawful or unfair practice (EXHIBITS 9, 10, 11, 12).

121. Defendant violated § 407.020 of the MMPA when it either concealed, omitted or suppressed the fact that the researchers involved in the clinical studies made citation to, or referenced the retracted studies as supportive of the results allegedly obtained in the remaining studies making the studies which were not retracted questionable as to the validity, reliability and statistical significance of the results obtained, when Defendant knew, or upon reasonable inquiry would have known of such citations to the retracted studies, making such representation an unlawful or unfair practice.

VI. Violations of the MMPA-Unfair Practices- Defendant's Website link to - www.cera-q.com.

122. Defendant violated § 407.020 of the MMPA by engaging in a deceptive practice when it identifies on the side of its box/packaging, that "detailed results can be found at www.Cera-Q.com" and such website identifies the study #2 on that webpage as

supportive of Defendant's representations that Natrol Cognium is "Clinically Proven" when Defendant knew, or upon reasonable inquiry would have known that the clinical study in question was retracted for fabrication/fraud, making such representation an unlawful or unfair practice (EXHIBITS 11 & 12).

123. Defendant violated § 407.020 of the MMPA by engaging in a deceptive practice when it identifies on the brochure contained within the box/packaging, that "detailed results can be found at www.Cera-Q.com" and such brochure identifies: "The majority of studies were randomized, double-blind, placebo-controlled studies and meet the highest level of evidence for claims support as stated by both the FDA and FTC. The studies were published in 11 peer-reviewed reports. A list of studies can be found on www.cera-q.com." when Defendant knew, or upon reasonable inquiry would have known that clinical study #2 listed on the website was retracted for fabrication/fraud, and that the website did not identify 11 peer reviewed reports, and that one study was repeated twice, and two of the studies were part of a "combined report" that included a retracted study, making such representation an unlawful or unfair practice (EXHIBITS 3, 10, 11, 12, 21).

124. Defendant violated § 407.020 of the MMPA by engaging in a deceptive practice when it links consumers to the website www.cera-q.com :

> CERA-Q IS BACKED BY 9 HUMAN CLINICAL TRIALS DEMONSTRATING SIGNIFICANT COGNITIVE IMPROVEMENTS ACROSS A WIDE RANGE OF AGES IN JUST 3 TO 4 WEEKS. CLICK TO LEARN MORE ABOUT THESE CLINICALLY DEMONSTRATED RESULTS.

-when Defendant knew, or upon reasonable inquiry would have known that only eight (8) clinical studies were identified, and that clinical study #2 listed on the website was retracted for fabrication/fraud, and two of the studies were part of a "combined report"

that included a retracted study, making such representation an unlawful or unfair practice (EXHIBIT 20, 21, 10, 11, 12).

125. Defendant violated § 407.020 of the MMPA by engaging in a deceptive practice when it links consumers to the website www.cera-q.com on the web page titled "Clinical Studies", which again touts the existence of clinical data:

> Comprising bioactive peptides with a unique amino acid profile, Cera-Q is backed by 9 published human clinical trials and in vitro data, all of which demonstrate Cera-Q's support of memory, learning, and general cognitive function across a wide range of ages, from children to the elderly. These studies show significant results in 3-4 week trials, demonstrating that Cera-Q is a powerful natural solution to help improve brain health at every age.

-when Defendant knew, or upon reasonable inquiry would have known that only eight (8) clinical studies were identified, and that clinical study #2 listed on the website was retracted for fabrication/fraud, and two of the studies were part of a "combined report" that included a retracted study, and that one study was repeated twice, making such representation an unlawful or unfair practice (EXHIBIT 21, 10, 11, 12).

126. Defendant violated § 407.020 of the MMPA by engaging in a deceptive practice when it links consumers to the website www.cera-q.com on the web page titled "FAQS" and the question appears "Is Cera-Q Beneficial for All Ages?" with the answer:

> The published research on Cera-Q demonstrates safety and efficacy across a full range of ages in normal, healthy people representative of the general population. Children, high school and college students, adults from 13-70 years old, and seniors over 70 years old were studied in nine separate studies. They were given standardized and scientifically accepted tests to measure benefits and changes for different kinds of shorty-term memory, learning skills, and complex tasks, measures typically used in IQ tests. Significant improvements were demonstrated at both intake levels (200 and 400 mg daily in two divided doses) in just three to four

weeks- a short time for seeing results.

-when Defendant knew, or upon reasonable inquiry would have known that only eight (8) clinical studies were identified, and that clinical study #2 listed on the website was retracted for fabrication/fraud, and two of the studies were part of a "combined report" that included a retracted study, and that one study was repeated twice, making such representation an unlawful or unfair practice (EXHIBIT 22, 21, 10, 11, 12)(Emphasis added).

VII. Violations of the MMPA-Unfair Practices – Defendant's Press Releases concerning Natrol Cognium

127. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated March 7, 2017 that "Natrol Cognium is the only brain health supplement with a proven nutrient backed by 9 clinical trials that show statistically significant improvements in memory and cognition in four weeks or less" -when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBIT 23, 9, 10, 11).

128. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated March 7, 2017 that "We're especially proud of the research and clinical studies that support that the ingredients in Cognium can improve cognitive health"- when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification that did not support that the ingredients in Cognium can improve cognitive health, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice

(EXHIBIT 23 p.3, 9, 10, 11).

129. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated June 12, 2017 that the product was "Backed by nine human clinical trials, Natrol Cognium Improves Memory and Cognition" when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification that did not support such representation, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBIT 24 p.1, 9, 10, 11).

130. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated June 12, 2017 that "This breakthrough product is specifically formulated to keep your mind sharp and your memory strong. Backed by nine human clinical studies, the active ingredient in Natrol Cognium has shown statistically significant improvements in memory and cognition in as little as four weeks."- when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification that did not support such representation, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBIT 24 p.2, 9, 10, 11).

131. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated June 29, 2017 that "The active ingredient in the product itself is tested in nine human clinical trials, and this is the key component of our messaging to ensure that our target feels that the product is credible and proven" - when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification that did not support such representation, when Defendant knew, or upon reasonable inquiry

would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBIT 25, 9, 10, 11).

132. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated June 29, 2017 that "Cognium is backed by 9 human clinical studies that show statistically significant improvements in memory and cognition in as little as four weeks. Results have been published in respected, peer-reviewed journals." -when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification that did not support such representation, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 25, 9, 10, 11).

133. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated June 29, 2017 that "Cognium has been show to be safe and effective in a wide variety of age groups. While our advertising is targeted towards the senior population, adults of all ages will benefit. It is something that should be taken daily and it has a cumulative effect over time." -when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification that did not support such representation, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 25, 9, 10, 11).

134. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated June 29, 2017 that "With Cognium, as with any product we bring to market, we need to make sure that our benefits and claims are truthful and not misleading. That's not only to comply with FTC guidelines, but also consistent with

ethical and responsible business management." -when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification that did not support such representation, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 25, 9, 10, 11).

135. Defendant violated § 407.020 of the MMPA when it represented and/or advertised in its press release dated June 29, 2017 that:

> For Cognium, we specifically selected an ingredient that had nine human clinical studies that showed statistically significant improvements in memory and other cognitive functions. The clinicals were high quality studies, with the bulk being randomized, placebo-controlled, double blind studies- high quality studies- that used scientifically accepted measures and tests for cognitive performance and that were published in respected peer-reviewed journals. Additionally, we formulated Cognium to ensure we used a clinical doses and our usage instructions mirror those used in the clinical studies. Our claims and are product are consistent with what was used and what was shown in the studies."

-when in fact at least two (2) clinical studies were retracted for data manipulation and fabrication/falsification that did not support such representation, when Defendant knew, or upon reasonable inquiry would have known of such retraction, making such representation an unlawful or unfair practice (EXHIBITS 25, 9, 10, 11).

COUNT 2.
UNJUST ENRICHMENT

136. Plaintiff Vitello incorporates paragraphs 1 through 135 of the Complaint as if directly reproduced herein.

137. Defendant received a benefit from the sale and purchase of Cognium by Plaintiff Vitello as described above.

138. Such benefit was provided to Defendant by Plaintiff at her expense.

139. Allowing Defendant to keep such benefit would be unjust, requiring Defendant to return such benefit to Plaintiff Vitello.

CLASS ACTION ALLEGATIONS

140. Plaintiff Vitello incorporates paragraphs 1 through 139 of the Complaint as if directly reproduced herein.

141. **Class Definition:** Plaintiff brings this claim on behalf of the class defined as follows:

Missouri Subclass: All persons who are citizens of Missouri and reside in Missouri on or after March 7, 2017 that purchased Cognium, either through an online seller or from a retail location in the State of Missouri.

Nationwide Class: All persons residing in the United States except Missouri on or after March 7, 2017 that purchased Cognium, either through an online seller or from a retail location in that persons respective state.

142. **Numerosity:** The putative class described above is so numerous that joinder of all members is impractical, as the class includes consumers across the State of Missouri who have purchased Defendant's product, Cognium. Upon information and belief, Plaintiff Vitello alleges that there are more than one hundred (100) members of the class in the State of Missouri, and more than one hundred (100) members of the class in all other states.

143. **Commonality/Predominance:** Questions of law and fact common to the putative class predominate over any questions affecting individual putative class members. The predominate common questions include, but are not limited to:

a) Whether Defendant violated the Missouri Merchandising Practices Act when it advertised its product, Cognium claiming that it was supported by "Nine Human Clinical Trials" when in fact two (2) of those clinical trials were retracted for fraud/fabrication, and data manipulation.

b) Whether Defendant violated the Missouri Merchandising Practices Act when it failed to notify the consumers/class members that two of the original Cognium Clinical Studies had been retracted for fraud/fabrication and data manipulation.

c) Whether Defendant violated the Missouri Merchandising Practices Act when it continued to sell its product advertising "nine human studies" and "nine clinical studies" when Defendant repeatedly altered its website reducing the number of Cognium Clinical Studies from 9, to 8, then 5 and then to 4 studies.

d) Whether Defendant violated the Missouri Merchandising Practices Act when it advertised that Cognium produced "statistically significant improvements in memory and cognition" when two (2) of the nine (9) Cognium Clinical Studies were retracted for fraud/fabrication and data manipulation and Defendant altered the number of studies posted on its webpage from 9, to 8, to 5 to 4.

e) Whether Defendant must disgorge the benefits received from Plaintiff Vitello and the putative class members from the sale of the Cognium.

f) Whether Defendants' violations were with evil motive or reckless indifference to the rights of the putative class members and give rise to an award of punitive damages.

144. **Typicality:** Plaintiff Vitello's claim for relief under the MMPA is typical of that of all other members of the putative class- Defendant offered its product for sale in the State of Missouri and other states making numerous representations concerning its cognitive enhancing effects that were backed by 9 Clinical Trials/Human Studies, which Plaintiff Vitello and other putative class members purchased.

145. **Representation of Putative Class:** Plaintiff Vitello will fairly and adequately protect the interest of the putative class. Plaintiff has retained counsel experienced in handling class

actions and other complex litigation. Neither Plaintiff nor Plaintiff's counsel have any interests which might cause them not to vigorously pursue this action.

146. A class action is an appropriate method for the fair and efficient adjudication of this controversy. The interest of class members in controlling the prosecution of separate claims is small because it is not economically feasible to bring individual actions, which would result in litigation brought in multiple venues across the State of Missouri and across the United States for claims that involve the purchase of Cognium for approximately $20.00.

147. **Superiority:** Class action treatment is superior to the alternatives for fair and efficient adjudication of the controversy alleged herein. Such treatment will permit a large number of similarly situated persons as described above to prosecute their claims in a single forum simultaneously and without duplication of effort and expense that numerous individual actions would entail, with the resulting risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct.

148. **Certification under Rule 23(b)(1)(A):** Individual adjudication of Plaintiff Vitello's claim and that of the putative class members would prejudice Defendant by requiring this Court to issue a ruling that may be inconsistent with rulings of different Courts in different venues, creating a conflict for Defendant whereby they would be ordered to act or conform in a manner that is incompatible with different court orders. For example, if this Court should issue a judgment finding that Defendant violated the MMPA when it advertised or represented that Cognium is backed by "9 Clinical Trials" or has "proven results" and another court deny one or more putative class members relief under the

MMPA, it would prejudice Defendants whereby they would not recognize or realize which order should be followed.

149. **Certification under Rule 23(b)(1)(B):** The prosecution of separate actions by separate individual members of the putative class would create the risk of adjudications in respect to other members that would substantially impair or impede their ability to protect their interests, due to a finite amount of funds available by Defendant to compensate Plaintiff Vitello and the putative class members for what may in fact amount to multiple violations of the MMPA for each class member that would have a dollar value that will exceed Defendant's ability to pay out to Plaintiff and the putative class members unless such action is maintained as a class action. A class action is necessary to protect this limited fund of money available to compensate Plaintiff and the putative class members.

150. **Certification under Rule 23(b) (2):** Defendants have acted on grounds generally applicable to the class by continuing to obfuscate, omit and misrepresent to the class members the existence of the studies that were retracted for fraud/fabrication and data manipulation making final injunctive or declaratory relief necessary –preventing Defendants' from disseminating any further advertising on its product packaging, container brochure and website any claim that the results are "clinical proven" or that such product is backed, or supported by "nine human clinical trials" or "clinical trials"- appropriate with respect to the class as a whole.

151. **Certification under Rule 23(b)(3):** Questions of law and fact common to class members predominate over any questions affecting only individual members as described above. A class action is superior to other available methods for fairly and efficiently adjudicating this controversy as the primary legal issue is whether or not Defendant's representation of

"nine clinical trials", "nine human studies", and "nine clinical studies" constitutes a deceptive/unfair practice under the MMPA, and the predominate factual analysis or inquiry is whether or not Defendant's representations in this regard were made to the putative class members, which will permit a large number of similarly situated persons to prosecute their common claims in this forum simultaneously and without duplication of effort and expense that numerous individual actions would entail. Matters pertinent to these findings include:

a) **Class Members' Interests:** The class members' interests in individually controlling the prosecution or defense of separate actions is low, as a class action under the MMPA is best suited for the means of protecting the interests of all consumers in a uniform manner without subjecting such members to inconsistent or varying adjudications with the additional expenses associated with such litigation.

b) **Extent and Nature of any Litigation:** There is no current litigation pending against Defendant concerning its product Cognium.

c) **Desirability of Forum:** Plaintiff Vitello's claims arise in the Eastern District of Missouri making this Court the appropriate forum for this litigation and Defendant also conducts business in St. Louis, Missouri offering Cognium for sale at retail locations and online, making it desirable to conduct litigation in this Court.

d) **Difficulties in Managing a Class Action:** No difficulties exist for managing this as a class action, as three (3) law firms are involved in prosecuting this matter with experience in class action litigation and complex litigation.

WHEREFORE, Plaintiff Christine Vitello, on behalf of herself and the putative class prays for the following relief:

A. An order certifying the Class as defined above;

B. An injunction requiring Defendants to: 1) cease advertising that Natrol Cognium is backed by 9 clinical studies on its box/packaging, bottle and brochure; 2) to inform consumers on its website www.cogniummind.com of the existence of the retracted studies; 3) to inform consumers on its website www.cogniummind.com that the studies were reduced from 9, to 8, to 5 to 4; 4) cease and desist from advertising/representing that Natrol Cognium is "clinically proven"; 5) cease linking or advertising that additional information on Natrol Cognium can be found at www.cera-q.com .

C. An award of compensatory damages;

D. An award of punitive damages;

E. An award of reasonable attorneys' fees and costs; and

F. Such further and other relief the Court deems reasonable and just.

JURY DEMAND

Plaintiff demands trial by jury.

Respectfully submitted,

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